

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

UNIVERSITY OF
MASSACHUSETTS and CARMEL
LABORATORIES LLC,

Plaintiffs,

C.A. No. 17-868-CFC-SRF

V.

PUBLIC VERSION

L'ORÉAL USA, INC.,

Defendant.

**L'ORÉAL USA'S CONCISE STATEMENT OF FACTS IN SUPPORT
OF ITS SUMMARY JUDGMENT MOTION OF INDEFINITENESS
OF THE SKIN ENHANCEMENT CLAIM LIMITATION**

OF COUNSEL:

Eric W. Dittmann
Isaac S. Ashkenazi
Nicholas A. Tymoczko
Karthik R. Kasaraneni
PAUL HASTINGS LLP
200 Park Avenue
New York, New York 10166

Naveen Modi
Joseph E. Palys
PAUL HASTINGS LLP
2050 M Street N.W.
Washington, D.C. 20036

Dennis S. Ellis
Katherine F. Murray
Serli Polatoglu
BROWNE GEORGE ROSS LLP
2121 Avenue of the Stars, Suite 2800
Los Angeles, California 90067

Dated: September 11, 2020

Frederick L. Cottrell, III (#2555)
Jeffrey L. Moyer (#3309)
Katharine L. Mowery (#5629)
RICHARDS, LAYTON & FINGER, P.A.
One Rodney Square
920 N. King Street
Wilmington, Delaware 19801
(302) 651-7700
cottrell@rlf.com
moyer@rlf.com
mowery@rlf.com

*Attorneys for Defendant
L'Oréal USA, Inc.*

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TABLE OF EXHIBITS¹

Exhibit No.	Document
1	U.S. Patent No. 6,423,327, issued to Dobson, Jr. et al. on July 23, 2002
2	U.S. Patent No. 6,645,513, issued to Dobson, Jr. et al. on November 11, 2003
5	Declaration of Gerald B. Kasting, Ph.D., containing true and correct excerpts from the Expert Report of Professor Gerald B. Kasting, Ph.D., dated June 26, 2020
6	Declaration of Gerald B. Kasting, Ph.D., containing true and correct excerpts from the Expert Report of Professor Gerald B. Kasting, Ph.D., dated July 21, 2020
7	Declaration of Gerald B. Kasting, Ph.D., containing true and correct excerpts from the Reply Expert Report of Professor Gerald B. Kasting, Ph.D., dated August 7, 2020
12	Excerpts from the Rebuttal Expert Report of Bozena Michniak-Kohn, Ph.D. Regarding Validity, dated July 21, 2020
17	Excerpts from the deposition transcript of James Dobson, taken May 27, 2020
24	Excerpts from the prosecution history of U.S. Application No. 09/672,348 (later issued as U.S. Patent No. 6,423,327)
30	Excerpts from Plaintiffs' First Supplemental Responses and Objections to Defendant's First Set of Interrogatories, dated May 1, 2020

¹ "Ex. __" refers to exhibits attached to the Declaration of Nicholas A. Tymoczko in Support of L'Oréal USA, Inc.'s *Daubert* and Summary Judgment Motions, filed concurrently herewith.

I. THE PATENTS-IN-SUIT

1. United States Patent Nos. 6,423,327 (“the ’327 patent”) and 6,645,513 (“the ’513 patent”) (together, the “patents-in-suit”) both claim priority to the same parent patent application filed on October 26, 1998.

2. Claim 1 is the sole independent claim of both patents-in-suit, and recites: “*A method for enhancing the condition of unbroken skin of a mammal by reducing one or more of wrinkling, roughness, dryness, or laxity of the skin*, without increasing dermal cell proliferation, the method comprising topically applying to the skin a composition comprising a concentration of adenosine in an amount *effective to enhance the condition of the skin* without increasing dermal cell proliferation, wherein the adenosine concentration applied to the dermal cells is [numerical concentration].” (Ex. 1, 10:17-26; Ex. 2, 10:17-26.)²

3. The phrase “amount effective to enhance the condition of the skin” appears in the body of claim 1 of both patents-in-suit.

4. The remaining claim terms of the patents-in-suit all depend from claim 1 and therefore contain the same claim limitations as claim 1.

² Unless otherwise noted, all emphases have been added and all internal citations, modifications, and quotations have been omitted. The patents-in-suit share a specification and citations are generally provided for the ’327 patent only.

II. THE INTRINSIC RECORD DOES NOT DELINEATE HOW TO DETERMINE WHETHER THE CONDITION OF THE SKIN HAS BEEN ENHANCED

5. The claims do not describe what counts as, or how to determine, whether there has been a reduction in “one or more of wrinkling, roughness, dryness, or laxity of the skin.”

6. The specification states: “Adenosine or an adenosine analog enhances skin condition when there is a *noticeable decrease* in noticeable decrease [*sic*] in the amount of wrinkling, roughness, dryness, laxity, sallowness, or pigmentary mottling of the treated skin.” (*See* Ex. 1, 5:44-48; *see also id.* at 2:35-37.)

7. The specification further states: “Methods of measuring improvements in skin condition are well known in the art (see, e.g., Olsen et al., J. Amer. Acad. Dermatol. 26:215-24, 1992), and *can include subjective evaluations by the patient or a second party, e.g., a treating physician*. Objective methods *can* include skin topography measurements.” (Ex. 1, 5:48-54.)

8. The patents-in-suit thus recognize that subjective assessments may be used to determine whether the condition of the skin has been enhanced, but do not provide any guidance to inform any such subjective inquiry or which of the multiple methodologies to apply and when. (Ex. 5, ¶ 258.)

9. Plaintiffs' expert, Dr. Bozena Michniak-Kohn, has not disputed that a subjective assessment may be used to determine whether the condition of the skin has been enhanced. (*See* Ex. 12, ¶¶ 182-91.)

10. According to named inventor Dr. James Dobson, a subjective assessment may be used to determine whether adenosine has enhanced the condition of the skin within the meaning of the claims. (Ex. 17 at 135:4-18 ("The fact that you used adenosine on your own skin and observed that there was a decrease in elasticity and a diminution of fine lines and wrinkles, would that have satisfied the patent claims in the '327 and '513 patent? . . . THE WITNESS: Assuming so, yes. Q. (BY MR. ASHKENAZI) Okay. And the point being is that a subject[ive] assessment of a diminution of fine lines and wrinkles or decrease in elasticity does satisfy or qualify as enhancing the condition of the skin, as you've defined it in the patent; correct? . . . THE WITNESS: Yes.").)

11. Even when skin assessments are guided by specific parameters or grading scales (which is not the case in the patents-in-suit), they can and do produce conflicting results (Ex. 5, ¶¶ 259-62), which Dr. Michniak-Kohn has not disputed (Ex. 12, ¶¶ 182-91).

12. There are multiple other methods that may be used to assess whether skin condition has improved, which may produce different results. (Ex. 5, ¶¶ 261-62; Ex. 7, ¶¶ 101-03; Ex. 12, ¶¶ 185-88; Ex. 17 at 171:1-15.)

13. Dr. Dobson testified that there are multiple tests available to assess whether or not wrinkling or roughness has been improved, and that they may give conflicting results. (Ex. 17 at 171:1-15.)

14. The specification does not provide any guidance regarding how a person of ordinary skill in the art should choose among these various, conflicting methods. (Ex. 5, ¶¶ 258, 261-63; Ex. 7, ¶ 103.)

III. THE APPLICANTS AND PLAINTIFFS HAVE RELIED ON THE PREAMBLE AS A LIMITATION

15. During prosecution of the application leading to the '327 patent, the claim language “[a] method for enhancing the condition of unbroken skin of a mammal by reducing one or more of wrinkling, roughness, dryness, or laxity of the skin” was added in response to an office action rejecting a proposed claim directed to a “‘method of enhancing’ the skin condition” as “vague because it is not clear as to enhance from what and to achieve what effect.” (See Ex. 24 at CARMEL LABS_00000784, -791, -793; Ex. 6, ¶ 28.)

16. In adding this language, the Applicants identified the portion of the specification stating that skin is enhanced “when there is a noticeable decrease in noticeable decrease [*sic*] in the amount of wrinkling, roughness, dryness, laxity, sallowness, or pigmentary mottling of the treated skin,” and explained they were amending the claim to recite “a method for enhancing the condition of unbroken skin of a mammal by reducing one or more of wrinkling, roughness, dryness, or

laxity of the skin” (thereby removing “sallowness, or pigmentary mottling”). (*See* Ex. 24 at CARMEL LABS_00000791, -793; *see also id.* at CARMEL LABS_00000744-45.)

17. The Applicants then relied on this claim language to distinguish prior art during prosecution, stating that, “Applicants apply adenosine as a cosmetic approach to enhance the condition or complexion of the skin, whereas Cronstein describes a medical therapy for open wounds such as burns.” (*See* Ex. 24 at CARMEL LABS_00000796; Ex. 6, ¶ 28.)

18. Plaintiffs identified the preamble language as a “limitation[]” that the prior art allegedly did not disclose in an interrogatory response. (Ex. 30 at 31.)

19. In responding to L’Oréal USA’s contention that the preamble was indefinite, Plaintiffs never stated that it was not a limitation. (*Id.* at 39.)

Of Counsel:

Eric W. Dittmann
Isaac S. Ashkenazi
Nicholas A. Tymoczko
Karthik R. Kasaraneni
PAUL HASTINGS LLP
200 Park Avenue
New York, New York 10166
(212) 318-6000

Naveen Modi
Joseph E. Palys
PAUL HASTINGS LLP
2050 M Street N.W.
Washington, D.C. 20036
(202) 551-1700

Dennis S. Ellis
Katherine F. Murray
Serli Polatoglu
BROWNE GEORGE ROSS
LLP
2121 Avenue of the Stars
Suite 2800
Los Angeles, California 90067
(310) 274-7100

Dated: September 11, 2020

/s/ Katharine L. Mowery

Frederick L. Cottrell, III (#2555)
Jeffrey L. Moyer (#3309)
Katharine L. Mowery (#5629)
RICHARDS, LAYTON & FINGER, P.A.
One Rodney Square
920 N. King Street
Wilmington, Delaware 19801
(302) 651-7700
cottrell@rlf.com
moyer@rlf.com
mowery@rlf.com

Attorneys for Defendant L'Oréal USA, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on September 11, 2020, a true and correct copy of the foregoing document was filed with the Clerk of Court via CM/ECF which will send notification of such filing to counsel of record and I further certify that a true and correct copy of the foregoing document was caused to be served on the following counsel of record as indicated:

VIA ELECTRONIC MAIL:

Brian E. Farnan
Michael J. Farnan
919 North Market Street
12th Floor
Wilmington, DE 19801
(302) 777-0300
bfarnan@farnanlaw.com
mfarnan@farnanlaw.com

Matthew Lowrie
Foley & Lardner LLP
111 Huntington Avenue, Suite 2600
Boston, MA 02199
(617) 342-4000
mlowrie@foley.com

VIA ELECTRONIC MAIL:

William C. Carmody
Tamar E. Lusztig
Beatrice C. Franklin
Nicholas C. Carullo
Susman Godfrey LLP
1301 Avenue of the Americas, 32nd Floor
New York, NY 10019
(212) 336-8330
bcarmody@susmangodfrey.com
tlusztig@susmangodfrey.com
bfranklin@susmangodfrey.com
ncarullo@susmangodfrey.com

Justin A. Nelson
Susman Godfrey LLP
1000 Louisiana Street, Suite 5100
Houston, TX 77002
(713) 651-9366
jnelson@susmangodfrey.com

/s/ Katharine L. Mowery

Katharine L. Mowery (#5629)
mowery@rlf.com

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION

The foregoing L'ORÉAL USA, INC.'S CONCISE STATEMENT OF FACTS IN SUPPORT OF SUMMARY JUDGMENT MOTION OF INDEFINITENESS OF THE SKIN ENHANCEMENT CLAIM LIMITATION complies with the type-volume limitations of Paragraph 19(f) of the Scheduling Order (D.I. 46). The text of this statement, including footnotes, was prepared in Times New Roman 14-point. According to the word processing system used to prepare it, this statement contains 1,023 words, excluding the case caption, tables, and signature block.

September 11, 2020

/s/ Katharine L. Mowery

Katharine L. Mowery (#5629)